Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

To compare the effect of continuous care and educational intervention (home visit) over a nine-month period on the rate of re-admissions, health care costs and quality of life in heart failure patients discharged from hospital

Protocol summary

Summary

The present study aimed to compare the effect of continuous care and educational intervention (home visit) over a nine-month period on the rate of re-admissions, health care costs and quality of life in heart failure patients discharged from hospital. In this study, 110 available hospitalized patients with heart failure were selected and were simple randomly divided into two intervention and control groups. Inclusion criterion was heart failure diagnosed by a cardiologist while those with a chronic progressive disease, except heart failure, as well as those who were not trainable were excluded from the study. The intervention which was carried out by a trained nurse included training patients or their families about heart failure disease, drugs being used, self care plan, diet, signs of disease recurrence and improvement as well as changing patient's life style according to the disease and also enabling families to take on care needs. This continuous care and educational plan was carried out in four-home visits over a nine-month period for the patients in the intervention group. Quality of life at baseline and end of study was evaluated by SF36 questionnaires . The rate and cost of hospital readmission of patients in both groups were evaluated at the end of the study by an information form.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013012612279N1**
Registration date: **2013-09-16, 1392/06/25**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-09-16, 1392/06/25

Registrant information

Name

Hoseinali Mehralian

Name of organization / entity

Shahr -e-Kored University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of research,Shahr-e-Kored University of Medical Sciences

Expected recruitment start date

2006-10-27, 1385/08/05

Expected recruitment end date

2007-04-09, 1386/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To compare the effect of continuous care and educational intervention (home visit) over a nine-month period on the rate of re-admissions, health care costs and quality of life in heart failure patients discharged

from hospital

Public title
Continuous care and educational intervention and treatment costs and quality of life in heart failure patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria 1- Heart failure diagnosed by cardiologist 2- Ejection fraction less than 45% 3- Literacy 4- Full consent to participate in the study Exclusion criteria 1- Having chronic progressive disease except heart failure 2- Heart surgery 3- Lack of mental health 4- No accessibility to the patients 5- Medical staff
Age
From **30 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahr-e-Kored University of Medical Sciences
Street address
Shahrekord University of Medical Sciences, Kashani Ave, Shahrekord
City
Shar-e-Kored
Postal code
8815713471
Approval date
2005-07-23, 1384/05/01
Ethics committee reference number
1-5-1384

Health conditions studied

1

Description of health condition studied
Ischemic Heart Failure
ICD-10 code
I25.9
ICD-10 code description
Chronic Ischaemic heart diseases

Primary outcomes

1

Description
quality of life
Timepoint
Beginning and end of the study
Method of measurement
SF 36 questionnaire

2

Description
Hospital Readmission
Timepoint
During the study
Method of measurement
Hospital Admission Form

3

Description
health care costs
Timepoint
At the end of the study
Method of measurement
Health Care Costs Form

Secondary outcomes

empty

Intervention groups

1

Description
The intervention which was carried out by a trained nurse included training patients or their families about heart failure disease, drugs being used, self care plan, diet, signs of disease recurrence and improvement as well as changing patient’s life style according to the disease and also enabling families to take on care needs. This continuous care and educational plan was carried out in four-home visits over a nine-month period for the patients in the intervention group. SF36 questionnaire were completed for all participants at beginning and end of study.
Category
Behavior

2

Description
In control group, there was no intervention. SF36 questionnaire were completed for all participants at beginning and end of study.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar hospital affiliated shahr-e-kored Medical Sciences
Full name of responsible person
Hoseinali Mehralian
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Hajar hospital, Parastar Ave, Shahrekord
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor of research,Shahr-e-Kored University of Medical Sciences
Full name of responsible person
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Shar-e-Kored
Grant name
شهرکرد-خیابا کاشانی -معاونت پژوهشی دانشگاه علوم پزشکی شهرکرد
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of research,Shahr-e-Kored University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty